WOLTURNUS
Wheelchairs built for freedom

EU Declaration of Conformity

with the Medical Device Regulation (MDR) 2017/745

We,

Wolturnus A/S, Skalhuse 31, 9240 Nibe, Denmark - DK-MF-000025274

Name and Address of Manufacturer – Single Registration Number (SRN)

hereby, under our sole responsibility declare, that the product

W5

Category Name

with model names and reference

Basic UDI-DI: 57138250077U

Model
W5
W5 S
W5 XXL

is in conformity with the Medical Device Regulation (MDR) 2017/745 as class I medical devices based on Annex VIII and the following common specifications (CS) and standards

DS/EN ISO 14971:2019, ISO 13485:2016, DS/EN 12183:2022, ISO 7176-19:2008

Standards

The intended purpose: The W5 wheelchair is intended to provide mobility to persons who are unable to walk or who have a mobility problem. It is designed for individual use, and it can be operated either by the patient or by another person. W5 is a robust fixed frame wheelchair and can be used both indoors and outdoors.

This EU declaration of conformity was written according to Annex 4 in MDR, and all supporting documentation is retained at the premises of the manufacturer.

Manufacturer

March 31, 2025 - Nibe	Peter Libak, CEO	
Date and place of issue	*Name and position of authorized person*	*Signature of authorized person*